In re the application of: Vincent Ling et al.

Serial No.: 10/085906

Filed: February 27, 2002

For: POLYMORPHIC ELEMENTS IN THE COSTIMULATORY RECEPTOR LOCUS AND

USES THEREOF

Attorney Docket No.: GNN-5343CP2

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Group Art Unit: 1634

Examiner:

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Date of Signature and of Mail Deposit

Amy E. Mandragouras Reg. No. 36,207

Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

For the Examiner's convenience in reviewing this continuation-in-part application, Applicants submit a consolidated PTO Form 1449, listing all references cited during the prosecution of the parent application. References A1-D3 were previously cited and submitted to the Office in U.S. Application Serial No. 09/534061, filed March 24, 2000 (Atty. Docket No. GNN-5343CP), to which this application claims priority. In accordance with 37 CFR §1.98(d), these references are not enclosed herewith, but will be provided upon request. In addition, this

Group Art Unit: 1634

Information Disclosure Statement presents references E1-E4, not previously submitted to the Office, which are enclosed herewith.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed per se as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

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Attorney for Applicants

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Date: June 25, 2002

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Re:

U.S. Patent Application No.: 10/085906

POLYMORPHIC ELEMENTS IN THE COSTIMULATORY TECH CENTER 1600/2900

RECEPTOR LOCUS AND USES THEREOF

Inventors: Vincent Ling et al. Filed: February 27, 2002 Our Ref. No.: GNN-5343CP2

Dear Sir:

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I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement;
- 2. PTO Form 1449;
- 3. Copies of selected references cited in PTO Form 1449 (4); and
- A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

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Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Amy E. Mandragouras Registration No. 36,207 Attorney for Applicants

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	A1	5,364,759	11/1994	Caskey et al.	435	6	
	A2	5,369,004	11/1994	Polymeropoulos et al.	435	6	
	А3	5,378,602	1/1995	Polymeropoulos et al.	435	6	
	A4	5,468,610	11/1995	Polymeropoulos et al.	435	6	
	A5	5,753,442	5/1998	Tyan	435	6	
	A6	5,851,795	12/1998	Linsley et al.	435	69.1	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	Country	CLASS	SUBCLASS	TRANSLATION	
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			ORIGINALLY FILED				

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

A7	Awata, Takuya et al. "Association of CTLA-4 Gene A-G Polymorphism (IDDM12 Locus) With Acute-Onset and Insulin-Depleted IDDM as Well as Autoimmune Thyroid Disease (Graves' Disease and Hashimoto's Thyroiditis) in the Japanese Population" Diabetes 47:128-29 (1998)				
. A8	Badenhoop, K. et al. "Genetic markers in diagnosis and prediction of relapse in Graves' disease" Exp. Clin. Endocrinol. Diabetes 104(Suppl. 4):98-100 (1996)				
A9	Balzano, Christine et al. "CTLA-4 and CD28: Similar Proteins, Neighboring Genes" <i>Int. J. Cancer Suppl.</i> 7:28-32 (1992)				
A10	Barbesino, Giuseppe et al. "Linkage Analysis of Candidate Genes in Autoimmune Thyroid Disease: 1. Selected Immunoregulatory Genes" <i>J. Clin. Endocrinol. & Metab.</i> 83(5):1580-84 (1998)				
A11	Barton, A. et al. "Polymorphic CTLA-4 Alleles are not Associated with Rheumatoid Arthritis (RA)" Eur. J. Immunogenet. 25(1):59, Abstract No. 4.3 (Feb. 1998)				
A12	Braun, J. et al. "CTLA-4 promoter variants in patients with Graves' disease and Hashimoto's thyroiditis" <i>Tissue Antigens</i> 51(5):563-66 (1998)				
A13	Buonavista, N. et al. "Molecular Linkage of the Human CTLA4 and CD28 Ig-Superfamily Genes in Yeast Artificial Chromosomes" <i>Genomics</i> 13(3):856-61 (July 1992)				
A14	Chapiro, J. et al. "Thérapie génique en oncologie: applications au cancer du poumon" ["Gene therapy in oncology: applications to lung cancer"][French] Revue Des Maladies Respiratoires 13(5):467-76 (Oct. 13, 1996)(Abstract attached)				
Colucci, Francesco et al. "Apoptosis resistance of nonobese diabetic peripheral lympl linked to the <i>Idd5</i> diabetes susceptibility region" <i>Proc. Natl. Acad. Sci. USA</i> 94(16):86 1997)					
A16	Dariavach, Piona et al. "Human Ig Superfamility CTLA-4 gene: chromosomal localization and identity of protein sequence between murine and human CTLA-4 cytoplasmic domains" <i>Eur. J. Immunol.</i> 18:1901-05 (1988)				
Examiner	Date Considered				

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8		Delchinani, Ki	aus et al. All Mise I NELF	in the numan CTLA4 Fromo	tor" <i>Biochem. Bi</i>	ophys.					
В	2	4	Res. Commun. 225:817-18, Article No. 1256 (Aug. 23, 1996) Djilali-Saiah, I. et al. "CTLA-4 gene polymorphism is associated with predisposition to coeliac								
		disease" Gut 4	disease" Gut 43:187-89 (1998)								
В	3		riss. et al. "No Major Role e With IDDM" <i>Diabetes</i> 47	for the <i>CTLA-4</i> Gene in the <i>I</i> :125-27 (Jan. 1998)	Association of A	utoimmu	ıne				
В	4		•	hism of the Cytotoxic T Lympsease" <i>J. Clin. Endocrinol. M</i>			in				
		(1997)	•		, ,						
В	15			Confers Genetic Susceptibility inol. Metabol. 82(1):143-46 (ease an	d to				
В	6	Donner, Horst	et al. " <i>CTLA4</i> Gene Haplo	types Cannot Protect From II	DDM in the Pres	ence of					
В	17			rman Families" Diabetes 47: ve DNA sequences and com							
	18		s 18:1577-85 (1997)								
ľ	"			mativity of 'Meaningless' Sim nome Scanning" <i>Biol. Chem</i> .							
	,	801 (Dec. 1994)	•							
8	19	Friedmann, T.	"The maturation of human	gene therapy" Acta Paediatr	ica 85:1261-65 ((1996)					
В	110	1 '		28 Activated Lymphocyte Mo ce, Message Expression, Ge		•	ted				
			Location" <i>J. Immunol.</i> 147:		ale Structure, an	iu					
В	111		e and Gough, Stephen C. sease" <i>Clin. Sci.</i> 93:479-9	L. "Genetic susceptibility to to	he development	of					
В	112			c association of a human C7	LA-4 promoter						
			•	isease in either population-ba	ased case-contr	ol or					
В	113		tudies" Clin. Endocrinol. 49 et al. "Genetic association	n of CTLA-4 to myasthenia gr	ravis with thymo	ma"J					
		Neuroimmunol	88:192-98 (1998)								
l [₿]	114	· ·	•	morphism at COL3A and Cinvitro CMI status in healthy			ne				
		preliminary stu	dy" Hum. Genet. 100:43-5	0 (1997)							
8	115			yte antigen-4 (CTLA-4) gene isease in English patients" C			2				
		(1998)	autoimmune Audison's di	sease in English patients Ci	IIII. ENGOCHNOI. 4	19.009-1	3				
В	116	· ·	"A CTLA-4 gene polymorp pothyroidism" Clin. Endoc	phism is associated with both	Graves' diseas	e and					
В	17	Krokowski, Ma	rcin et al. "An association of	of CTLA-4 gene A/G polymor							
		insulin-depend 22:262-65 (199		population of Central Poland	d" Cent. Eur. J. I	lmmuno	<i>l</i> .				
В	118	Krokowski, M.	et al. "CTLA-4 Gene Polyn	norphism is Associated with I	•	IDDM i	in a				
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TRADEMOOTHERS (including Author, Title, Date, Pertinent Pages, Etc.) Krokowski, M. et al. Diabetol. Pol. 5(Suppl. 1):45-52 (1998)(Abstract Only) C2 Marron, Michele P. et al. "Insulin-dependent diabetes mellitus (IDDM) is associated with CTLA4 polymorphisms in multiple ethnic groups" Hum. Molec. Genet. 6:1275-82 (1997) СЗ Mehrian, Ruty et al. "Synergistic Effect Between IL-10 and bcl-2 Genotypes in Determining Susceptibility to Systemic Lupus Erythematosus" Arthritis & Rheum. 41(4):596-602 (1998) Nisticò, Lorenza et al. "The CTLA-4 gene region of chromosome 2q33 is linked to, and C4 associated with, type 1 diabetes" Human Mol. Genet. 5(7):1075-80 (1996) Owerbach, David et al. "Analysis of Candidate Genes for Susceptibility to Type I Diabetes: A C5 Case-Control and Family-Association Study of genes on Chromosome 2q31-35" Diabetes 46:1069-74 (June 1997) Ç6 Polymeropoulos, Michael H. et al. "Dinucleotide repeat polymorphism at the human CTLA4 gene" Nucleic Acids Res. 19(14):4018 (1991) Pozzilli, P. et al. "Non-HLA genes and the susceptibility to insulin dependent diabetes: the role of **C7** the CTLA-4 gene" Acta Diabetol. 33:250-52 (1996) Sale, Michèle M, et al. "Association of Autoimmune thyroid Disease with a Microsatellite marker for the Thyrotropin Receptor Gene and CTLA-4 in a Japanese Population" Proc. Assoc. Amer. Physicians 109(5):453-61 (1997) C9 Seidl, C. et al. "CTLA codon 17 dimorphism in patients with rheumatoid arthritis" Tissue Antigens 51:62-66 (1998) She, Jin-Xiong "Genetic Factors in Type 1 Diabetes: A Complex Disease" J. Clin. Ligand Assay 21(3):272-81 (Fall 1998) C11 Todd, J.A. "Genetics of Type I Diabetes" Pathol. Biol. 45:219-27 (Mars 1997) C12 Todd, John A. and Farrall, Martin "Panning for gold: genome-wide scanning for linkage in type 1 diabetes" Hum. Mol. Genet. 5:1443-48 (1996) Tomer, Yaron and Davies, Terry F. "The genetic susceptibility to Graves' disease" Baillieres Clin. C13 Endocrinol. & Metab. 11(3):431-50 (Oct. 1997) Tomer, Yaron et al. "Mapping of a Major Susceptibility Locus for Graves' Disease (GD-1) to C14 Chromosome 14q31" J. Clin. Endocrinol. Metab. 82(5):1645-48 (1997) Vaidya, B. et al. "Affected Sibling-Pair Analysis of the CTLA-4 Locus in Graves' Disease" J. Endocrinol. 156(Suppl.):P319 C16 Valère, Thomas "Thérapie génique: le point sur les essais cliniques" M.S. Medecine Sciences 12:73-83 (1996) C17 Van der Auwera, B. et al. "CTLA-4 Gene Polymorphism Confers Susceptibility to IDDM Independently from Genetic and Immune Disease Markers" Diabetoligica 39 (Suppl. 1):A61 C18 Van der Auwera, B.J. et al. "CTLA-4 gene polymorphism confers susceptibility to insulindependent diabetes mellitus (IDDM) independently from age and from other genetic or immune disease markers" Clin. Exp. Immunol. 110:98-103 (1997) C19 Waterman, E.A. et al. "A study of the association between a polymorphism in the CTLA-4 gene and postpartum thyroiditis" Clin. Endocrinol. 49:251-55 (1998) Examiner Date Considered Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation *EXAMINER: if not in conformance and not considered. Include copy of this form with next communication to applicant.

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			1 diabetes in contrast to A → G transition	within exon 1" Biomedicai Le	ett. 58:163-68 (1	1998)	
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